



LAHIVE
&
COCKFIELD
L L P

COUNSELLORS AT LAW
28 STATE STREET
BOSTON, MASSACHUSETTS 02109-1784
TELEPHONE (617) 227-7400
FAX (617) 742-4214
lc@lahive.com

JOHN A. LAHIVE, JR. (1928-1997)
THOMAS V. SMURZYNSKI
RALPH A. LOREN
GIULIO A. DeCONTI, JR.
ANN LAMPORT HAMMITTE
ELIZABETH A. HANLEY
AMY BAKER MANDRAGOURAS
ANTHONY A. LAURENTANO
KEVIN J. CANNING
JANE E. REMILLARD
DeANN FORAN SMITH
PETER C. LAURO
DEBRA J. MILASINCIC, Ph.D.
DAVID J. RIKKERS
DAVID R. BURNS
JOHN S. CURRAN
SEAN D. DETWEILER
MEGAN E. WILLIAMS, Ph.D.

LISA M. DIROCCO
HATHAWAY P. RUSSELL *
MARIA LACCOTRIPE ZACHARAKIS, Ph.D.
MERIDETH C. ARNOLD
DANIELLE L. HERRITT
EUIHOON LEE **

SENIOR COUNSEL
JAMES E. COCKFIELD

OF COUNSEL
JEREMIAH LYNCH
WILLIAM A. SCOFIELD, JR.
SIBLEY P. REPERT
JEANNE M. DIGIORGIO
CYNTHIA L. KANIK, Ph.D.

PATENT AGENTS
THEODORE R. WEST
CYNTHIA M. SOROOS
PETER W. DINI, Ph.D.
JONATHAN M. SPARKS, Ph.D.

TECHNICAL SPECIALISTS
CATHERINE M. BISHOP
JACOB G. WEINTRAUB
CRISTIN E. HOWLEY, Ph.D.
JILL ANN MELLO, Ph.D.
DEBORAH L. NAGLE, Ph.D.
ANNE JACQUELINE NOWAK, Ph.D.
ANDRINA WILLIAMS ZINK

* Admitted in TX only
** Admitted in CT only

July 30, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RECEIVED

AUG 04 2003

Re: U.S. Patent Application No.: 10/008264
For: *T-Bet Compositions and Methods of Use Thereof*
Inventors: Glimcher, Laurie H. *et al.*
Filed: December 3, 2001
Our Ref. No.: HUI-040CP

TECH CENTER 1600/2900

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Information Disclosure Statement;
2. PTO Form 1449;
3. Copies of references cited in PTO Form 1449 (9);
4. Copy of the International Search Report (2 pages);
5. Copy of the European Examination Report (3 pages); and
6. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

July 30, 2003

Date

Megan E. Williams, Esq., Reg No. 43,270

Respectfully submitted,
LAHIVE & COCKFIELD, LLP

Megan E. Williams, Esq.
Attorney for Applicants
Registration No. 43,270



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Glimcher, Laurie H., *et al.*

Serial No.: 10/008,264

Filed: December 3, 2001

For: T-Bet Compositions and Methods of Use Thereof

Attorney Docket No.: HUI-040CP

Group Art Unit: 1642

Examiner: Not Yet Assigned

RECEIVED

AUG 04 2003

TECH CENTER 1600/2900

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

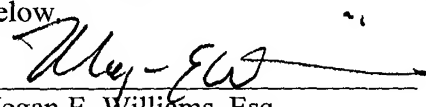
Certificate of First Class Mailing (37 CFR §1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date set forth below.

July 30, 2003

Date of Signature and of Mail Deposit

By:


Megan E. Williams, Esq.
Registration No. 43,270
Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

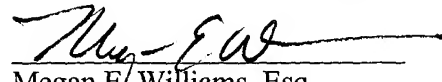
Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form 1449, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. Reference ID Nos. A1, 2, 3, 8, and 6 were cited in an International Search Report during the prosecution of PCT/US02/38514 mailed April 18, 2003 which corresponds to the above referenced application. Reference ID Nos. A4, 5, 7, and 8 were cited in a Examination Report during the prosecution of European Patent Application No. 00 939 546.8 dated December 9, 2002 which

also corresponds to the above referenced application. A copy of the reports and each cited publication is enclosed.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee for consideration of \$180.00 as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

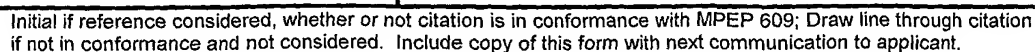
Respectfully submitted,
LAHIVE & COCKFIELD, LLP


Megan E. Williams, Esq.
Registration No. 43,270
Attorney for Applicants

28 State Street
Boston, MA 02109
(617) 227-7400

Date: July 30, 2003

GAD/MEW/JXS/mxh
Enclosures





✉ EPA/EPO/OEB
D-80298 München
☎ +49 89 2399-0
TX 523 656 epmu d
FAX +49 89 2399-4465

Europäisches
Patentamt

European
Patent Office

Office européen
des brevets

Generaldirektion 2

Directorate General 2

Direction Générale 2

Frohwitter, Bernhard, Dipl.-Ing.
Patent- und Rechtsanwälte,
Possartstrasse 20
81679 München
ALLEMAGNE

Telephone Numbers:

Primary Examiner +49 89 2399-8546
(substantive examination)

Formalities Officer / Assistant +49 89 2399-8051
(Formalities and other matters)



Application No. 00 939 546.8-2405	Ref. P81067PCTEP	Date 09.12.2002
Applicant PRESIDENT AND FELLOWS OF HARVARD COLLEGE		

Communication pursuant to Article 96(2) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(1) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

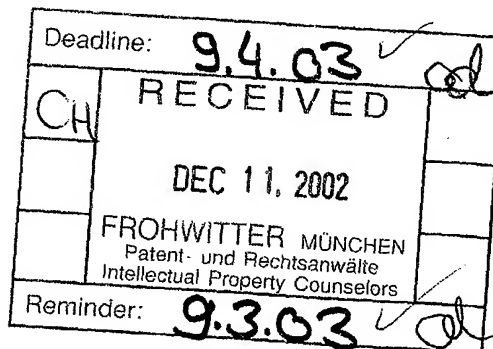
from the notification of this communication, this period being computed in accordance with Rules 78(2) and 83(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (Rule 36(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Article 96(3) EPC).



GIEBELER K M
Primary Examiner
for the Examining Division



Enclosure(s): 2 page/s reasons (Form 2906)

Datum
Date
09.12.2002Blatt
Sheet
Feuille
1Anmelde-Nr.:
Application No.:
Demande n°:
00 939 546.8

The examination is being carried out on the **following application documents**:

Text for the Contracting States:

AT BE CH LI CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE

Description, pages:

1-84 as published

Claims, No.:

1-32 as published

Drawings, sheets:

1/27-27/27 as published

1. The following documents are cited:

D1: CELL, vol. 100, March 2000, pages 655-669

D2: DATABASE EMBL SEQUENCES Accession No. AF093098, 16 Oct 1999

D3: NEURON, vol. 15, no. 1, July 1995, pages 63-78

D4: TRENDS IN GENETICS, vol. 15, no. 4, April 1999, pages 154-158

2. The documents D1 and D2 indicated in the search report as P-documents are not to be regarded as state of the art according to Article 54(2) EPC, as the date of priority claimed can be allowed for the relevant parts of the present application, cf. Articles 54(2) and 89 EPC.

3. The application does not meet the requirements of Article 84 EPC, because claims 1, 4-13 and 18-32 are not clear.

3.1. The present application relates to a Th1 specific transcription factor (termed "T-bet"), which upon retroviral transduction into Th2 and Tc2 primary T-cells redirects them into Th1 and Tc1 cells, respectively.



However, the protein is not clearly defined in the independent claims of the application by its structural and functional features. In fact, the independent claims merely refer to the term "T-bet protein" which is an arbitrary name not known by person skilled in the art at the present priority date. Pursuant to Article 84 EPC, the claims have to define the invention as clearly as possible. Consequently, the structural and functional features of the protein have to be stated in the independent claims.

- 3.2. Claims 18-20 do also not clearly define the claimed protein since it is not stated in said claims that the "at least 70(90)% identity" is over the entire length, and any known protein, especially the T-box proteins (see D3 and D4) share short stretches of amino acid identity to SEQ ID NOs: 2 and 4. In the absence of a clear limitation over the prior art proteins, said claims thus have to be considered to lack novelty. It appears that the description does also not state that the percentage of amino acid identity should be over the entire length.
- 3.3. Claims 14-20 should apparently refer to claim 13, not 12.
4. Claims 27 and 28 relating to "an agent capable of detecting an indicator of T-bet activity" and to "an agent that modulates T-bet activity" lack sufficiency of disclosure (Article 83 EPC) and support by the description (Article 84 EPC) since the agents are neither disclosed over the entire breadth of the claims nor clearly defined.
5. The applicant is requested to file new claims which take account of the above comments and to adapt the description accordingly.

Incorporation by reference is not provided for by the EPC. Such reference should therefore be deleted from the description, see also the Guidelines C-II 4.18.

The statement on page 1, lines 3-7 is also not in line with the EPC and should likewise be deleted.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/38514

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C12Q 1/02, 1/68; G01N 33/53

US CL : 435/6, 7.8, 29

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/6, 7.8, 29

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00/73453 A1 (PRESIDENT AND FELLOWS OF HARVARD COLLEGE) 07 December 2000 (07.12.2000), see entire document, especially pages 6, 43-44, 47, 50, 55, and 87.	101-122
A	WO 99/11783 A2 (SMITHKLINE BEECHAM PLC) 11 March 1999 (11.03.1999), see entire document.	101-122
A	US 6,031,078 A (KHODADOUST) 29 February 2000 (29.02.2000), see entire document.	101-122
A	SZABO et al. A Novel Transcription Factor, T-bet, Directs Th1 Lineage Commitment. Cell. 17 March 2000, Vol. 100, pages 655-669, see entire document.	101-122
A	MULLEN et al. Role of T-bet in Commitment of Th1 Cells Before IL-12-Dependent Selection. Science. 08 June 2001, Vol. 292, pages 1907-1910, see entire document.	101-122



Further documents are listed in the continuation of Box C.



See patent family annex.

Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

03 April 2003 (03.04.2003)

Date of mailing of the international search report

18 APR 2003

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. 703-305-3230

Authorized officer

Terry A. McKelvey

Telephone No. 703-308-0196

INTERNATIONAL SEARCH REPORT

PCT/US02/38514

Continuation of Box I Reason 2:

the claims are drawn to use of agents that modulate the expression and/or activity of T-bet. These agents are drawn to compounds whose activity is determined by assays, which compounds are not structurally described in a way such that a meaningful, comprehensive search of the claims can be made.

Continuation of B. FIELDS SEARCHED Item 3:

EAST (USPAT, EPO, JPO, Derwent), Dialog OneSearch (biotech databases)

search terms: t-bet, t box, expressed, t cells, brachyury, tbx1-6, t-brain-1, tbr-1, assay?, measur?, test?, screen?, modulat?, identif?, IFN, tec kinase, TGF, inhibit?, stimulat?, agonist?, antagonist?